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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,625	12/21/2001	Sabine Stumvoll	25401-5	1495

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/027,625	STUMVOLL ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-21 and 23-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-21 and 23-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 9-21 and 23-29 are pending and under consideration.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/16/2007 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 9-21 and 23-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The phrases: "in an individual known to be allergic" claimed in claim 9; and "in an individual known to be allergic, from among a variety of possible allergen sources" claimed in claim 23 represent a departure from the specification and the claims as originally filed.

Applicant's amendment filed on 08/24/2006 does not point to the specification for support for the newly added claim limitations. In particular, the amendment does not provide support for the limitations "in an individual known to be allergic" claimed in Claim 9 and "in an individual known to be allergic, from among a variety of possible allergen sources" claimed in Claim 23. The specification and the claims as originally filed do not provide a clear support for these claim limitations.

Applicant's arguments filed on 05/16/2007 have been fully considered, but are not found persuasive.

Applicant argues that the examples set forth in the application demonstrate methods for serologically identifying individuals who have serum IgE specific for ragweed, mugwort and/or Parietaria pollen among weed pollen allergic subjects who are known to be allergic.

Examiner argues that the species of individuals known to be allergic to weed pollen does not read on the genus of all individuals known to be allergic. A subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads, see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). Therefore, applicants do not

have written support in the application as filed for the terms 'in an individual known to be allergic' and 'in an individual known to be allergic among a variety of possible allergen sources.'

5. Claims 9-21 and 23-29 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for serologically identifying Parietaria allergic patients with improved accuracy among individuals previously known to be weed pollen allergic comprising contacting the serum from the individual with Par j1 or Par j 2 and determining the presence of IgE binding to Par j 1 or Par j 2 and identifying that the individual is allergic to Parietaria species if the serum contains IgE binding to Par j1 or Par j 2, does not provide reasonable enablement for a method for serologically identifying with improved accuracy in **an individual known to be allergic** [to] **the actual sensitizing allergen source from among a variety of possible allergen sources** containing cross-reactive proteins or epitopes, comprising selecting **an individual known to be allergic**; contacting serum from the individual with **a pure allergen component derived from one of the variety of possible allergen sources** the **pure allergen component having limited or no cross-reactivity**, determining, in said serum, the presence of lgE binding to said **pure allergen component**; and identifying **the source from which said pure allergen component is derived** as the actual sensitizing allergen source if the serum contains IgE binding to said **pure allergen component** of claim 9; further comprising selecting an allergy treatment involving **extract, proteins or peptides derived from said actual sensitizing allergen source** of claim 10; wherein the **allergen component is derived from pollen of a plant species** of claim 11; wherein the plant species is **a weed species** of claim 12; wherein the weed species is mugwort, ragweed or a Parietaria species of claim 13; the weed

species is Parietaria judaica of claim 14; wherein the allergen component is Par j 1 or Par j 2 of claim 15; wherein the allergen component is recombinant of claim 16; wherein the pure allergen component is **derived from pollen of a plant species** of claim 17; wherein the pure allergen component is **derived from a weed species** of claim 18; wherein the weed species is mugwort, ragweed or a Parietaria species of claim 19; wherein the weed species is Parietaria judaica of claim 20; wherein the pure allergen component is Par j I or Par j 2 of claim 21; A method for serologically identifying with improved accuracy sensitivity to Parietaria pollen in **an individual known to be allergic**, from among **a variety of possible allergen pollen sources**, comprising selecting **an individual known to be allergic** contacting a serum sample from the individual with a pure allergen component of Par j 1 or Par j 2; determining, in said serum, the presence of lgE binding to said pure allergen component; and identifying the individual as sensitive to Parietaria pollen if the serum contains lgE binding to said pure allergen component of claim 23; wherein the allergen component is Par j 2 of claim 24; wherein the allergen component is recombinant Par j 2 of claim 25; A method for serological diagnosis for **an individual known to be allergic** of **an actual sensitizing allergen pollen source** from among **a variety of possible allergen pollen sources containing cross-reactive proteins or epitopes** with improved accuracy, comprising selecting **an individual known to be allergic to pollen** contacting a serum sample from the individual with **a pure allergen component derived from one of the variety of allergen pollen sources which contain cross- reactive proteins or epitopes**, the pure allergen component having limited or no cross-reactivity; determining, in said serum, the presence of IgE binding to said **pure allergen component**: and identifying the **allergen pollen source** from which said **pure allergen component** is derived as the actual **sensitizing allergen**

pollen source if the serum contains IgE binding to said **pure allergen component** of claim 26; wherein the allergen source from which the pure allergen component is derived is mugwort, ragweed or a Parietaria species of claim 27; wherein the pure allergen component is recombinant Par j 2 of claim 28; wherein the individual has previously been diagnosed as allergic to weed pollen, and wherein the pure allergen component is Par j 2 of claim 29.The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification has not disclosed adequate support for the claimed 'pure allergen component' that is 'derived from one of a variety of allergen sources', 'derived from pollen of a plant species' or 'derived from a weed species' other than Par j 1 and Par j 2. These terms encompass an extraordinarily large amount of possible pure allergen components, both

discovered and unknown and include non-peptide allergens including metals and drugs. The derivative may also be a mutant of a naturally occurring allergen component. the application does not have support for any other pure allergen component for use in the claimed invention other than Par j1 and Par j 2. It is highly unpredictable as to what pure allergen components can be used in the claimed method other than Par j 1 and Par j 2.

The specification has not adequately disclosed any 'individual known to be allergic' to any plant, weed or structure thereof. It is difficult, if not impossible to predict what allergen structure as taught by Malandain (PTO-892, Reference U). There is no characteristic sequence fro a B- or a T-epitope that has been found so far and it is not surprising since APCs must detect whole molecules before cutting them into pieces. Thus, recognizing an allergen depends on certain properties of the whole, genuine protein, these clues being lost in T cell epitopes. The instant specification has not adequately disclose the the method encompassing any predicting allergy to any allergen from any allergen source.

There is also insufficient support in the specification for the species of all individuals known to be allergic. The specification discloses weed pollen allergic subjects and a subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads, see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working

examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

6. Claims *9-21 and 23-29* are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a method for serologically identifying Parietaria allergic patients with improved accuracy among individuals previously known to be weed pollen allergic comprising contacting the serum from the individual with Par j1 or Par j 2 and determining the presence of IgE binding to Par j 1 or Par j 2 and identifying that the individual is allergic to Parietaria species if the serum contains IgE binding to Par j1 or Par j 2.

Applicant is not in possession of a method for serologically identifying with improved accuracy in **an individual known to be allergic** [to] **the actual sensitizing allergen source from among a variety of possible allergen sources** containing cross-reactive proteins or epitopes, comprising selecting **an individual known to be allergic**; contacting serum from the individual with **a pure allergen component derived from one of the variety of possible allergen sources** the **pure allergen component having limited or no cross-reactivity**, determining, in said serum, the presence of lgE binding to said **pure allergen component**; and identifying **the source from which said pure allergen component is derived** as the actual

sensitizing allergen source if the serum contains IgE binding to said **pure allergen component** of claim 9; further comprising selecting an allergy treatment involving **extract, proteins or peptides derived from said actual sensitizing allergen source** of claim 10; wherein the **allergen component is derived from pollen of a plant species** of claim 11; wherein the plant species is **a weed species** of claim 12; wherein the weed species is mugwort, ragweed or a Parietaria species of claim 13; the weed species is Parietaria judaica of claim 14; wherein the allergen component is Par j 1 or Par j 2 of claim 15; wherein the allergen component is recombinant of claim 16; wherein the pure allergen component is **derived from pollen of a plant species** of claim 17; wherein the pure allergen component is **derived from a weed species** of claim 18; wherein the weed species is mugwort, ragweed or a Parietaria species of claim 19; wherein the weed species is Parietaria judaica of claim 20; wherein the pure allergen component is Par j I or Par j 2 of claim 21; A method for serologically identifying with improved accuracy sensitivity to Parietaria pollen in **an individual known to be allergic**, from among **a variety of possible allergen pollen sources**, comprising selecting **an individual known to be allergic** contacting a serum sample from the individual with a pure allergen component of Par j 1 or Par j 2; determining, in said serum, the presence of IgE binding to said pure allergen component; and identifying the individual as sensitive to Parietaria pollen if the serum contains IgE binding to said pure allergen component of claim 23; wherein the allergen component is Par j 2 of claim 24; wherein the allergen component is recombinant Par j 2 of claim 25; A method for serological diagnosis for **an individual known to be allergic** of **an actual sensitizing allergen pollen source** from among **a variety of possible allergen pollen sources containing cross-reactive proteins or epitopes** with improved accuracy, comprising selecting **an individual known to be**

allergic to pollen contacting a serum sample from the individual with **a pure allergen component derived from one of the variety of allergen pollen sources which contain cross-reactive proteins or epitopes**, the pure allergen component having limited or no cross-reactivity; determining, in said serum, the presence of IgE binding to said **pure allergen component**: and identifying the **allergen pollen source** from which said **pure allergen component** is derived as the actual **sensitizing allergen pollen source** if the serum contains IgE binding to said **pure allergen component** of claim 26; wherein the allergen source from which the pure allergen component is derived is mugwort, ragweed or a Parietaria species of claim 27; wherein the pure allergen component is recombinant Par j 2 of claim 28; wherein the individual has previously been diagnosed as allergic to weed pollen, and wherein the pure allergen component is Par j 2 of claim 29.

Applicant has disclosed only a method for serologically identifying Parietaria allergic patients with improved accuracy among individuals previously known to be weed pollen allergic comprising contacting the serum from the individual with Par j1 or Par j 2 and determining the presence of IgE binding to Par j 1 or Par j 2 and identifying that the individual is allergic to Parietaria species if the serum contains IgE binding to Par j1 or Par j 2. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method.

Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the

Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 9-21 and 23-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Duro et al. (Reference AD; IDS filed 07/01/2002) for reasons of record set forth in the Office Action mailed 02/25/2005

Applicant's arguments and Colombo declaration filed on 05/16/2007 have been fully considered but are not found persuasive

Applicant argues by declaration that Duro et al. teaches the Par j 2 protein is a major allergen. The declaration also argues that Duro et al. does not suggest to one of ordinary skill in the art a method for serological diagnosis for an individual known to be allergic of an actual sensitizing allergen source from among a variety of possible allergen sources containing cross-reactive proteins or epitopes with improved accuracy. Duro et al. does not disclose or suggest that the Par j 2 allergen is not cross-reactive with allergen components from other allergen sources. Duro et al. does not teach or suggest using Par j 2 or any other purified allergen component in methods for diagnosis of the actual sensitizing source from a variety of possible allergen sources as the present application claims. Stumvoll et al. showed that the Parietaria pollen contains independent families of allergens with different immunological relevance. In

particular, Stumvoll et al. teaches the presence of cross-reactive and species-specific allergens in Parietaria pollen. The Par j 2 allergen belongs to the latter family and neither this discovery nor a method employing it were disclosed or suggested by the Duro et al. reference. Applicant also argues that the terminology is important in this application because the term 'pure allergen component' refers to Par j 1 or Par j 2, 'allergen source' refers to a species of plant. Applicant argues that the failing of Duro et al is that the reference does not disclose limited or no cross reactivity. Applicant argues that the present methods are for accurately identifying the actual sensitizing allergen source (for example, the actual sensitizing pollen) from among a variety of allergen sources (for example, various weed pollens) for an individual who is already known to be allergic. Applicant goes on to say that the present methods are for identifying to which particular allergen source, for example, to which pollen, the individual is allergic and not for generally diagnosing allergy. Applicant argues that Duro et al. fails to teach a method for serologically identifying the actual sensitizing allergen source among a variety of possible allergen sources because Duro et al. is directed to a single allergen source. Applicant further argues that Duro et al., do not teach a method for selection of an allergy treatment involving extract, proteins or peptides derived from said allergic sensitizer.

The declaration of Mr. Colombo filed on 05/16/2007 under 37 C.F.R. 1.132 is insufficient to overcome the rejection under 102(b) for the following reason: The Examiner understands applicant's position that the serum used in Duro et al. was from Parieta judaica allergic patients and only Parieta judaica derived peptides were used, so Applicant feels that there is no way that any determination is being made among allergen sources. However, as

evidenced by the Applicant's own specification and claims, Par j 2 is diagnostic of Parieta judaica pollen allergy. Since only 82% of the patients reacted with Par j 2, 18% of the patients are inherently NOT allergic to Parieta judaica afterall and therefore must be allergic to another allergen from another allergen source. Duro et al. need not "teach" that Par j 2 is non-cross reactive. It is well known that peptides have specific properties that are related to their length and sequence. It is highly unpredictable that two peptides that lack 100% length and sequence identity will have the same properties. Therefore, it is inherent in this teaching, as all other teachings, that the properties of a given protein or peptide are novel and specific to that protein or peptide, unless evidence is presented to the contrary. Duro et al. does not need to teach that Par j 2 does not cross react with other polypeptides from other allergen sources since it is not presumed that it would cross react given that it is not the exact same peptide as that from other allergen sources.

Examiner maintains the position that Duro et al. teaches contacting serum with recombinant Par j 2 to detect pollen allergy. Duro et al., further teaches that the characterization of the recombinant antigen is a preliminary step for use of said protein therapeutically. The prior art teaches all of the method steps of the claimed invention and as such anticipates the claimed invention. The preamble adds no additional limitations to the claims since the same product was used in the same method steps for identifying allergens from patients.

Duro et al., teaches serologically (from serum) identifying the actual sensitizing allergen (Parieta judaica pollen) from a variety of possible allergen sources (all allergens other than Parieta judaica pollen as the evidenced by the specification which teaches that Par j 2 does not cross react amongst other weed allergen species), since the IgE of the Parieta judaica pollen sensitive patients was used and 82% of the Parieta judaica pollen sensitive patients serums' IgE reacted with recombinant Par j2. If the Par j2 is a pure allergen component without cross-reactivity with use as a diagnostic tool for diagnosing that specific allergy, then this information shows that 18% of the patients were not allergic to P. judaica. Therefore, the results inherently show that 18% of the patients were allergic to another allergen from a variety of allergen sources other than P. judaica, presumably with cross-reacting proteins or epitopes to P. judaica. Additionally, Duro et al. inherently teaches serologically identifying the actual sensitizing allergen (recombinant Par j2) from a variety of allergen sources since Par j2 is the allergen selected amongst all allergens to perform the experiments. It is also noted that amongst the Parieta judaica allergic patients' serum that were tested, the IgE of only 82% of patients reacted with Par j2.

In addition, Duro et al., does teach that previous to their disclosed method that the P. judaica allergen was known to have at least 9 allergens having different molecular weights and in order to plan a diagnostic and therapeutic approach to allergic reaction a preliminary step is to purify and characterize (i.e. serologically identify with improved accuracy) each major allergen by cloning the allergen and testing its immunoreactivity in blood from patients with P. judaica reactivity. This method anticipates the method according to claim 10 that recites the selection of

the allergy treatment involves extract, protein or peptides derived from the allergen source. The preliminary steps above include peptides and proteins and are necessary to plan a diagnostic and therapeutic approach as taught by Duro et al.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 7, 2006

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

Maher M. Haddad

MAHER M. HADDAD
PRIMARY EXAMINER